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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,512	11/08/2007	Justin Hanes	JHUC-P01-021	3582

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ROPES & GRAY LLP
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EXAMINER	
SGAGIAS, MAGDALINE K	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,512	HANES ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 5-10, 12-13, 17-22 drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, wherein the bioactive agent is encapsulated in the polymer core.

Group II, claim(s) 3, drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, wherein the bioactive agent is disposed on the surface of the polymeric particle.

Group III, claim(s) 4, drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, wherein the bioactive agent is covalently coupled to the polymer core.

Group IV, claim(s) 11, drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, further comprising a targeting moiety

Group V, claim(s) 16, drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, wherein the surface-altering agent is polyethylene glycol.

Group VI, claim(s) 23, drawn to a method for transfecting a cell comprising administering to the cell a polymeric particle of claim 1 or 16.

Group VII, claim(s) 24, drawn to a method for transfecting a cell comprising administering to the cell a polymeric particle of claim 17.

Group VIII, claim(s) 24, drawn to the method of claim 20, wherein the polymeric particle in the pharmaceutical composition passes through a mucosal barrier in the patient.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: **De Campos et al,** (European Journal of Pharmaceutical Sciences, 20: 73-81, 2003 (IDS)) discloses a PEG versus a chitosan coating on the interaction of drug colloidal carriers with ocular mucosa (p 74-76). Thus, the technical feature of a polymer core with a bioactive agent and a surface-altering agent is not special and the groups are not so linked under PCT Rule 13.1. Additionally, the claimed methods in groups VI-VIII have distinct steps, produce different results which are not coextensive and which do not share the same technical feature.

The inventions of group's I-V are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in group I have distinct physiological functions than group II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The inventions of the groups VI-VIII are distinct each from the other because they are drawn to methods that have distinct steps, require separate compositions for practice and

produce different product or results. For example, the steps for transfecting a cell comprising administering to the cell a polymeric particle of claim 1 or 16 cannot be used in the method of transfecting a cell comprising administering to the cell a polymeric particle of claim 17.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
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